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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/935,513 | 08/22/2001 | Harlan Edgar Shannon | X-10576A | 9165 |

25885 7590 10/21/2004

ELI LILLY AND COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER

CRIARES, THEODORE J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 10/21/2004

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,513

Applicant(s)

SHANNON ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44, 60-67 and 81-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-44 is/are allowed.
- 6) ☒ Claim(s) 60-67 and 81-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7, 14</u> . | 6) <input type="checkbox"/> Other: _____ |

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CLAIMS 1-44, 60-67 and 81-91 ARE PRESENTED FOR
EXAMINATION

The Terminal Disclaimer filed December 29, 2003, has been accepted by the United States Patent Office and duly recorded.

Applicants' claims 60-67 and 81-91 are drawn to compositions of olanzapine and a known compound used in the treatment of psychiatric disorders.

After a review of the composition claims and the remarks filed August 27, 2002 (8/27/02) the following action is deemed proper in view of applicants' amendments to the claims and newly cited art to be applied in view of the amendments to the claims. .

Claims 1-44 are allowed since the preamble in the claims have been given weight by the examiner since they recite a method and composition for treating pain.

Applicant's arguments with respect to claims 60-67 and 81-91 have been considered but are moot in view of the new ground(s) of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections under 35 U.S.C 112, first and second paragraph are withdrawn in view of applicants' argument that olanzapine has utility in the treatment of pain and as an anti-psychotic compound.

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Claim Rejections - 35 USC § 103

Claims 60-67 and 81-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admissions in view of Krushinski, Jr., et al. (5,576,321) ('321).

Applicants admit at column 1, lines 42-55 that olanzapine is known to be useful in treatment of psychotic disorders. '321 teaches at column 113, line 33 to column 114, line 54 applicants' claimed known compounds of claims 60-67 and 81-91 have known activity in the treatment of psychotic disorders since they known serotonin reuptake inhibitors and mixed serotonin-norepinephrine reuptake inhibitors. The compositions of claims 60-67 and 81-91 are drawn to compositions which can be present in a ratio of one to one which are within applicants' claimed ratios.

Therefore, as stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960).

As this court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in the prior art. "

In this application the skilled artisan would have been to combine olanzapine with known compounds that are serotonin reuptake inhibitors and mixed serotonin-norepinephrine reuptake inhibitors to treat psychotic disorders since each is known to treat psychotic disorders.

Applicants' data has been reviewed and it is insufficient to determine an unexpected synergistic effect with the combination of known compounds that have a

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common characteristic. There is a failure to establish a synergistic combination of the claimed active agents as taught by applicants at column 1, lines 43-54 of the subject Reissue application.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 60-64 and 81-85 are rejected under the judicially created doctrine of double patenting over claims 1-20 of U. S. Patent No. 6,147,072 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claims are drawn to a method of treating a

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patient suffering from or susceptible to psychosis, acute mania etc with compositions claimed in the instant application. It would be obvious to use applicants' claimed active combination of agents, to treat the claimed psychotic disorders claimed in the present application. This obvious type double Patenting rejection is deemed proper.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

CONCLUSION

The claims are drawn to compositions that have anti-psychotic activity. One of ordinary skill in the art would have been motivated to combine the claimed active agents to form an anti-psychotic formulation since they have similar activity. There is a lack of any showing of synergistic activity.

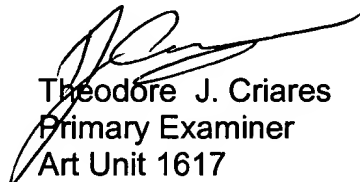
The cited patents, other than '321, are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Theodore J. Criares
Primary Examiner
Art Unit 1617

TJC
10/12/04